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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

August 8, 1997

97-PHI-39

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

GEN. SPEC.
RELEASE
F# _____ DATE 8/8/97
Reviewed by:

Gary Truckenmiller
RR #1
P.O. Box 278
Watsontown, Pennsylvania 17777

Dear Mr. Truckenmiller:

An inspection of your farm, located on RR #1 in Watsontown, Pennsylvania, conducted by Food and Drug Administration (FDA) investigator Gregory E. Beichner on June 12, 1997, confirmed that you offered a cow for sale for slaughter for human food in January 1997 in violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about January 29, 1997, you offered a cow, back tag #1352, for slaughter as human food at [redacted]. The animal was purchased and was slaughtered by [redacted] on January 29, 1997. United States Department of Agriculture (USDA) testing of the animal revealed the presence of 22.0 ppm neomycin in its kidney tissue. This is considered to be an illegal tissue residue since the tolerance for neomycin in edible bovine kidney tissue is 7.2 ppm. The presence of neomycin in the edible kidney tissue from your animal at the concentration level detected renders the food from the animal to be adulterated.

Our investigation also found that you hold animals under conditions that permit those bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for assuring that animals have been treated with drugs which have been approved for use in those species; for assuring that drugs are used in a manner not contrary to the

directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

The above is not intended as an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused or participated in causing the adulteration of an animal that was offered for sale to a slaughterhouse that ships beef in interstate commerce, is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen working days, state the reasons for the delay and the timeframe in which correction will be achieved. Please include copies of any available documentation demonstrating that correction has been accomplished.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Very Truly Yours,

Diana J. Kolaitis
District Director
Philadelphia District

jci

cc: Dr. Max A. Van Buskirk, Director
PA State Bureau of Animal Industry
Agriculture Building
2301 North Cameron Street
Harrisburg, PA 17120

cc: Dr. F.R. Rellosa
USDA Northeast Regional Office
701 Market Street
2B South
Mellon Independence Center
Philadelphia, PA 19102-1516